DermaPort

510(k) Summary

Company Name: DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CSA 91355

NOV 30 2007

Contact: Buzz Moran, President
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Summary Date: April 30, 2007

Trade Name: DermaPort Percutaneous Vascular Access System (PVAS)

Common Name: Hemodialysis Catheter, Implanted

Classification Name: 21 CFR 876.5540 Blood Access Device and Accessories, Class III, Product Code: MSD

Predicate Device(s):

510(k) Number: K994105
Manufacture: MEDCOMP®
Trade Name: Medcomp Hemo-Flow Catheter

510(k) Number: K062901
Manufacture: Med-Conduit Inc.
Trade Name: HemoCath II

1.0 Description of Device

The DermaPort Percutaneous Vascular Access System (PVAS) is designed to facilitate catheter placement, reposition, and exchange procedures while maintaining the catheter attachment, bacterial barrier, and fixation functions of the predicate catheter fibrous cuff. The main component of the PVAS is a metal port which is implanted into the subcutaneous tunnel at the catheter exit site on the chest wall. The hemodialysis catheter passes through the metal port which acts as a percutaneous conduit, into the subcutaneous tunnel, and then into the central venous system in the usual fashion. The metal surface of the PVAS port has a porous, tissue integrating coating which allows ingrowth of tissue to anchor the PVAS port. The PVAS port holds the hemodialysis catheter in place.

The DermaPort Percutaneous Vascular Access System (PVAS) consists of the following types of components:

1. Implanted Hemodialysis 14.5 F Catheter (24 cm, 28 cm or 32 cm lengths)
2. Guidewire; 0.038 inch (70 cm or 100 cm lengths)
3. 16F Tearaway Set Griplock Hub
4. 12F Polyethylene Dilator
5. 14F Polyethylene Dilator
6. Clear Female Dust Cover
7. Injection Caps
8. 18 GA x 2.7" Cyrolite Introducer Needle
9. Tunneler with Tri ball tip
10. Tunneler Sleeve
11. DermaPort Blade
12. Commercially available alcohol pad
13. Commercially available adhesive wound dressing
14. Peel-away Sheath
15. DermaPort Percutaneous Vascular Access System (PVAS) Port

The catheter is identical to the HemoFlow catheter, with the exception that the fabric cuff on the HemoFlow catheter is omitted. The HemoFlow catheter is cleared to market by the FDA via 510(k) number K994105.

The Percutaneous Vascular Access System (PVAS™) has been developed to support central vascular access for hemodialysis and apheresis. The PVAS port consists of a percutaneous tubular conduit, through which a standard 14.5F polyurethane hemodialysis catheter enters the subcutaneous tunnel. An integral seal surrounds the catheter and prevents microbial migration along the catheter. The PVAS port is enclosed by a silicone anchor that braces the assembly to the skin, and an associated brake holds the catheter in place within the port. A tissue integrating biomaterial surrounds the port, providing anatomical fixation and prevention of microbial migration in a manner analogous to the fabric cuff of a tunneled catheter.

2.0 Intended Use of Device

The indication for use of the PVAS is consistent with the classification of 21 CFR 876.5540 Blood Access Device and Accessories, and the predicate Medcomp Hemo-Flow Catheter. The indication for use is:

> The DermaPort Percutaneous Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

3.0 Technological Characteristics

The PVAS technical characteristics and construction are substantially equivalent to the predicate device. The difference in construction was qualified with bench and animal testing.

4.0 Conclusions

The DermaPort, Inc. PVAS is substantially equivalent to the predicate device. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2007

Mr. Buzz Moran
President
DermaPort, Inc.
25102 Rye Canyon Loop, Suite 110
SANTA CLARITA CA 91355

Re: K071202
Trade/Device Name: DermaPort Percutaneous Vascular Access System (PVAS™)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: November 14, 2007
Received: November 15, 2007

Dear Mr. Moran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains an alcohol pad which is subject to regulation as a drug.

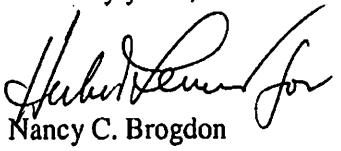
Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071202

Device Name: DermaPort Percutaneous Vascular Access System (PVAS)

Indications for Use:

The DermaPort Percutaneous Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071202